DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

9/19/d

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-03

October 4, 2001

FACILITY ID # 150631

Chris Hulin, Vice President
Atlantic Medical Center
Site: Memorial Hospital - Peninsula
264 South Atlantic Avenue
Ormond Beach, Florida 32176

Dear Mr. Hulin:

We are writing to you because on September 13, 2001, your facility was inspected by a representative of the State of Florida, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1, 2 and 3 findings at your facility:

Level 1: Your facility processed mammograms when Kodak processor, X-OMAT M35 or M35A-M, was out of limits for 18 days, i.e., processor QC records were missing for 18 of 23 days of consecutive operation during the month of August 2001 for the Kodak processor.

Level 2: Phantom QC records were missing for a minimum of two weeks for unit 2, General Electric Co., MAMMO room.

Corrective action before further exams for a failing image score, or a phantom background density, or density difference outside the allowable regulatory limits was not documented for unit 2, General Electric Co., MAMMO room.

Radiology technologist Susan Turner did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period (Susan Turner – 12.5 CEUs in 36 months).

Level 3: The fixer retention QC is not adequate for Kodak processor, X-OMAT M35, e.g., the fixer retention QC records were not completed at the required frequency.

The screen-film contact QC is not adequate for site Memorial Hospital-Peninsula e.g., the QC was not done at the required frequency.

The darkroom fog QC is not adequate for darkroom at site Memorial Hospital-Peninsula, e.g., the QC was not done at the required frequency.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and,

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to Timothy J. Couzins, Compliance Officer, U.S. Food & Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact D. Janneth Caycedo, Consumer Safety Officer, Boca Raton Resident Post, Food and Drug Administration at 561-338-5236, ext 23.

Sincerely yours,

Emma R. Singleton
Director, Florida District